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PART II:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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PICKLED, FERMENTED, ACIDIFIED AND LOW-ACID FOODS

Proposed Good Manufacturing Practices

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 90]

[Docket No. 75N-0332]

PICKLED, FERMENTED, AND ACIDIFIED FOODS

Emergency Permit Control

The Food and Drug Administration (FDA) proposes to add a new § 90.22 Pickled, fermented, and acidified foods (21 CFR 90.22) to provide requirements to ensure safe manufacture, processing, and packing procedures. Interested persons have until September 21, 1976 to submit comments.

After consideration of all comments received in response to this proposal, a final regulation will be published in the FEDERAL REGISTER. The Commissioner of Food and Drugs proposes that the final regulation be effective 60 days after date of publication.

The Commissioner issued, in the FEDERAL REGISTER of May 14, 1973 (38 FR 12720), and corrected in the FEDERAL REGISTER of May 30, 1973 (38 FR 14174), proposed definitions and procedures to govern implementation of the emergency permit control authority contained in section 404 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 344). In the FEDERAL REGISTER of January 29, 1974 (39 FR 3748), an emergency permit control regulation was published, which was amended in the FEDERAL REGISTER of April 1, 1974 (39 FR 11876). This regulation was drafted to apply to thermally-processed low-acid foods packaged in hermetically sealed containers primarily because of the potential health hazard from *Clostridium botulinum* toxin. Since the primary public health problem in pickled, fermented, and acidified foods is also toxin from C. *botulinum*, the Commissioner proposes to amend Part 90 (21 CFR Part 90) to provide for emergency permit control for pickled, fermented, and acidified foods.

From January 1972 through December 1975, pickled, fermented, or acidified foods were involved in 4 seizures, 38 recalls, and the issuance of 20 letters to foreign processors stating that their products would no longer be allowed to enter the United States.

The four seizures included two for bacterial spoilage, one for label violations, and one for an excessive amount of tin in the product. Two of the recalls were due to botulinum poisoning that occurred in acidified foods commercially processed in the United States. As a result of these botulinum poisonings, eight people became ill—seven from peppers and one from marinated mushrooms. The peppers were canned in a plant lacking a pH meter and adequate thermometers and were not properly acidified. The mushrooms were not entirely immersed in the acidification bath prior to packing in oil and, consequently, some of them were not acidified. Of the 36 remaining recalls, 34 involved products (31 imported peppers and pimientos, 2 domestic peppers and 1 imported hearts of palm) which were not acidified to a pH of 4.6 or lower. The other two recalls involved filth in domestic pickles but did not involve insufficient acidification.

Copies of information concerning the incidents related above have been placed on display in the office of the Hearing Clerk, Food and Drug Administration, as part of the record of this proceeding.

All these processors appeared to have lacked awareness of the importance of the technical processing that is critical to assuring a commercially sterile product. The hazard is such that the Commissioner believes it necessary to establish an emergency permit control regulation for this industry to protect the public health.

During the years 1899 through 1964, there were 29 reported outbreaks of botulism that resulted from eating home-canned foods—101 illnesses and 55 deaths were reported. The canned foods involved were pickled beets, peppers, pimientos, and pickles (Ref. 16). Even though these products were home-canned, the figures underscore the need for acidification for adequate processing.

If low-acid foods are to be held in hermetically sealed containers at ambient temperatures, the spores of *C. botulinum* must be destroyed by a high-temperature thermal process (240° F for example). Acid foods or normally low-acid foods that are acidified to an equilibrium pH of 4.6 or below may be held at ambient temperatures in hermetically sealed containers without such a heat treatment because the pH is sufficiently low to prevent the germination of the spores. In many cases, at least a low-temperature process (boiling water or below) must be used to destroy the vegetative cells. *C. botulinum* spores are not destroyed by such low-temperature processes and can produce toxin if the pH has not been reduced enough, or if it is allowed to rise above the level where the spores can reproduce.

Therefore, it is extremely important that the pH be carefully controlled by persons knowledgeable in the problems of canning and that a margin of safety be maintained.

Many articles have been published about acidity and the growth of *C. botulinum* in foods. A number of references concern the acidification of pimientos, a normally low-acid food that is acidified to permit safe processing at low temperature to make canned pimientos acceptable for sale (Refs. 1 through 5).

In such foodstuffs, where acidification or fermentation is relied upon to prevent growth of *C. botulinum*, the recommended maximum pH of 4.6 appears to provide an ample safety margin (Refs. 6, 7, and 8).

Salt-stock-fermented pickles may be stored safely in 10 percent salt solution until processed into finished pickles. This may be done because of the low water activity of the system (Refs. 9, 10, and 11).

Fermentation and salting procedures are set forth in a number of publications (Refs. 12 through 15).

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. The Commissioner has also carefully considered the inflation impact of the proposed regulation as required by Executive Order 11821, OMB Circular A-107, and interim guidelines issued April 1, 1975 by the Department of Health, Education, and Welfare, and no major inflation impact has been found. Copies of the FDA environmental and inflation impact assessments are on file with the Hearing Clerk, Food and Drug Administration.

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The references listed above have been placed on display for public review at the office of the Hearing Clerk, Food and Drug Administration.

Under the Federal Food, Drug, and Cosmetic Act (secs. 402, 404, 701, 52 Stat. 1046–1048 as amended, 1055–1056 as amended by 70 Stat. 19 and 72 Stat. 948 (21 U.S.C. 342, 344, 371) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FR of June 15, 1976 (41 FR 24262)), it is proposed that Part 90 be amended by adding the following new § 90.22, to read as follows:

§ 90.22 Pickled, fermented, and acidified foods.

(a) Inadequate or improper manufacture, processing, or packing of pickled, fermented, and acidified foods may result in the distribution in interstate commerce of processed foods that may be injurious to health. The harmful nature of such foods cannot be adequately determined after these foods have entered into interstate commerce. The Commissioner of Food and Drugs therefore finds that, in order to protect the public health, it may be necessary to require any commercial processor, in any establishment engaged in the manufacture, processing, or packing of pickled, fermented, and acidified foods to obtain and hold a temporary emergency permit provided for under section 404 of the Federal Food, Drug, and Cosmetic Act. Such a permit may be required whenever the Commissioner finds, after investigation, that the commercial processor has failed to fulfill all the requirements of this section, including registration and the filing of process information, and the mandatory portions of §§ 128g.4(e), 128g.7(b), (c)(1) and (2), (d), 128g.8(b), (c) and (d), 128g.10 and 128g.11 of this chapter. These requirements are intended to ensure safe manufacture, processing, and packing processes and to permit the Food and Drug Administration to verify that these processes are being followed. Such failure shall constitute a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the act to that establishment, pursuant to the procedures established in Subpart A of this part.

(b) The definitions in § 128g.1 of this chapter are applicable when such terms are used in this section.

(c)(1) *Registration and process filing.*—A commercial processor when first engaging in the manufacture, processing, or packing of pickled, fermented, and acidified foods in any state, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register and file with the Food and Drug Administration on Form FD–2962 (pickled, fermented, and acidified foods establishment registration and process filing) information including (but not limited to) his name, principal place of business, the location of each establishment in which such processing is carried on, the processing method in terms of acidity and pH control and, as necessary, conditions for heat processing and control of salt, sugar, and preservative levels, and a list of foods so processed in each such establishment: *Provided,* That the filing of such information does not constitute approval by the Food and Drug Administration of the content of the information filed, and that informaion concerning processes and other data so filed shall be considered trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905 (to the extent that they qualify as such under the provisions thereof). These forms are available from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch, HFF–342, 200 C St. SW., Washington, D.C. 20204, or at any Food and Drug Administration district office. The completed form shall be submitted to the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch, HFF–342, 200 C St. SW., Washington, D.C. 20204. Commercial processors presently so engaged shall register and file their processes within 60 days after the effective date of this regulation. Foreign processors shall register and file their processes prior to any offering of such foods for import into the United States. Commercial processors duly registered in accordance with this section shall notify the Food and Drug Administration not later than 90 days after such commercial processor ceases or discontinues the manufacture, processing, or packing of such foods in any establishment: *Provided,* That such notification shall not be required for temporary cessations necessitated by the seasonal character of an establishment's production or by temporary conditions including but not limited to labor disputes, fire, or acts of God.

(2) *Process adherence and information.*—(i) A commercial processor engaged in the processing of pickled, fermented, and acidified foods in any registered establishment shall process each food in conformity with the scheduled processes filed pursuant to paragraph (c)(1) of this section.

(ii) Process and pH information availability: When requested by the Food and Drug Administration in writing, a commercial processor engaged in processing of pickled, fermented, and acidified foods shall provide the Food and Drug Administration with any information concerning processes and procedures which the Food and Drug Administration deems necessary to determine the adequacy of the process: *Provided,* That the furnishing of such information does not constitute approval by the Food and Drug Administration of the content of the information filed and that the information concerning processes and other data so furnished shall be considered trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905 (to the extent that they qualify as such under the provisions thereof).

(d) A commercial processor engaged in the processing of pickled, fermented, and acidified foods shall promptly report to the Food and Drug Administration any instance of spoilage, process deviation, or contamination with microorganisms the nature of which has potential health-endangering significance where any lot of such food has in whole or in part entered distribution in commerce.

(e) A commercial processor engaged in the processing of pickled, fermented, and acidified foods shall prepare and maintain in his files a current procedure for use for products under his control and which he will ask his distributor to follow, including plans for recalling products that may be injurious to health; for identifying, collecting, warehousing, and controlling products; for determining the effectiveness of recalls; for notifying the Food and Drug Administration of any recalls; and for implementing recall programs.

(f) All plant personnel involved in acidification, pH control, heat treatment or other critical factors of the operation shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food protection principles, personal hygiene, plant sanitation practices, pH controls, and critical factors in acidification, and who has satisfactorily completed the prescribed course of instruction. The Commissioner will not withhold approval of any school qualified to give such instruction.

(g) A commercial processor engaged in the processing of pickled, fermented, and acidified foods shall prepare, review, and retain at the processing plant for a period of not less than 1 year, and at the processing plant or other reasonably accessible location for an additional 2 years, all records of processing, deviations in processing, pH, and other records specified in Part 128g of this chapter. Upon written demand during the course of a factory inspection pursuant to section 704 of the act by a duly authorized employee of the Food and Drug Administration, a commercial processor shall permit the inspection and copying by such employee of these records to verify the pH and the adequacy of processing.

(h) This section shall not apply to the commercial processing of any food processed under the continuous inspection of the meat and poultry inspection program of the Animal and Plant Health Inspection Service of the Department of Agriculture under the Federal Meat Inspection Act (34 Stat. 1256, as amended by 81 Stat. 584 (21 U.S.C. 601 et seq.)) and the Poultry Products Inspection Act

(71 Stat. 441, as amended by 82 Stat. 791 (21 U.S.C. 451 et seq.)).

(i) Imports: (1) This section shall apply to any foreign commercial processor engaged in the processing of pickled, fermented, and acidified foods and offering such foods for import into the United States except that, in lieu of providing for the issuance of an emergency permit under paragraph (a) of this section, the Commissioner will request the Secretary of the Treasury to refuse admission into the United States, pursuant to section 801 of the act, to any such foods which the Commissioner determines, after investigation, may result in the distribution in interstate commerce of processed foods that may be injurious to health as set forth in paragraph (a) of this section.

(2) Any such food refused admission shall not be admitted until the Commissioner determines that the commercial processor offering the food for import has complied with the requirements of this section and that such food is not injurious to health. For the purpose of assisting the Commissioner in making such determination, a duly authorized employee of the Food and Drug Administration shall be permitted to inspect the commercial processor's manufacturing, processing, and packing facilities.

(j) The following data and information submitted to the Food and Drug Administration pursuant to this section are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter:

(1) Manufacturing methods or processes, including quality control information.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

Interested persons may, on or before September 21, 1976, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 2, 1976.

SHERWIN GARDNER,
Deputy Commissioner of Food and Drugs.

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[21 CFR Part 128b]

[Docket No. 75N-0333]

THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Good Manufacturing Practice

The Food and Drug Administration is proposing to revise the good manufacturing practice regulation for low-acid canned foods under Part 128b (21 CFR Part 128b). Interested parties have until (September 21, 1976) to submit comments. Currently, Part 128b is applicable to some foods that are acidified to a pH of 4.6 or below. Because the heat processing of acidified foods is markedly different from that for normally low-acid foods, the Commissioner proposes that acidified foods be removed from Part 128b and that they be included in a new proposed Part 128g, which is published elsewhere in this issue of the FEDERAL REGISTER.

After consideration of all comments received in response to this proposal, a final regulation will be published in the FEDERAL REGISTER. The Commissioner proposes that the final regulation be effective 60 days after the date of publication.

In the preamble to the regulation promulgating Part 128b, published in the FEDERAL REGISTER of January 24, 1973 (38 FR 2398), the Commissioner, in referring to foods to which heat is applied primarily for some purpose other than to achieve commercial sterility, such as pasteurization, flavor development, or removal of moisture, stated that "* * * it was not the intent of the proposal to include such foods. Such foods will not be subject to coverage under the good manufacturing practice regulations * * *." A number of questions have since been asked as to which foods are in fact covered by the regulation.

The Commissioner has concluded that any thermally processed low-acid food that is packaged in hermetically sealed containers is included in the scope of Part 128b if such food is to be held at ambient temperature after processing. Ordinarily, pasteurized foods are stored and distributed under refrigeration. The Commissioner is aware that there are some low-acid canned foods with a water activity (a_w) greater than 0.85 for which thermal processes are sufficient to destroy non-spore-forming microorganisms, but for which thermal processes are insufficient to destroy spore-forming microorganisms. The growth of spore-forming microorganisms in the product may be prevented by the control of a_w, use of salt or other chemicals, or some unique characteristic of the food. Such foods include cheeses, cheese analogs, cheese sauces and spreads, syrups and toppings, canned cakes and breads, caviar and certain other salt cured products. FDA needs to review data which demonstrate that growth of microorganisms will not occur in these foods and ask that, upon request, scientific evidence be supplied to FDA that establishes that non-spore-forming organisms are destroyed by the thermal process and that spore-forming organisms will not grow in these foods under normal conditions of storage and distribution. The Commissioner believes that so much is unknown concerning a_w-controlled foods that it is in the public interest to require processors of such foods to register their plants and file their processes as directed in 21 CFR 90.20. He invites comments from any interested party in response to this proposal. The proposed §§ 128b.3(f) and 128b.6(i) are added to provide for proper preparation and thermal processing of the a_w-controlled foods to assure commercial sterility. A proposed modification of § 128b.10 provides for training in these unique aspects of preservation technology. Other mandatory provisions (i.e., §§ 128b.4, 128b.8, and 128b.9) shall apply to the manufacture, processing, and packing of these foods, as appropriate.

The Commissioner proposes other changes to update and clarify Part 128b, along with the proposed deletion of acidified fruits, vegetables, and vegetable products. Some of these changes would add new paragraphs and renumber others. Proposed Part 128g, published elsewhere in this issue of the FEDERAL REGISTER, would establish a good manufacturing practice regulation for pickled, fermented, and acidified foods.

The significant changes being proposed are listed section-by-section as follows:

1. *Section 128b.1.* The definition of "commercial processor" is expanded to state explicitly that the regulation includes pet food. The preamble of the January 24, 1973, FEDERAL REGISTER notice (38 FR 2398) stated that the Commissioner had always considered that the regulation should apply to the pet food industry, but no statement to that effect appears in the CFR itself.

Definitions for the terms "critical factor," "operating process," and "vacuum packed products" are added. These terms are currently used undefined in several places in the regulation. The definition of "low-acid foods" is revised to exclude those acidified foods that are now to be included in proposed Part 128g.

Since *C. botulinum* can grow and produce toxin in some products at a pH of 4.8, and because the Commissioner maintains that a safety factor of 0.2 pH units is necessary, he proposes to set an upper pH limit of 4.6 for all foods. All foods with a pH of 4.6 or less are to be excluded from coverage under Part 128b. The definition of "low-acid foods" currently in Part 128b excludes "tomatoes, pears, and pineapples * * * having a pH less than 4.7, and figs having a pH of 4.9 or below * * *." The Commissioner believes that available bacteriological data on tomatoes, pineapples, pears, and figs are not adequate to justify these exemptions and, therefore, proposes that these foods be covered under Part 128b if the pH of the raw product is greater than 4.6. The data submitted by National Canners Association concerning the effect of pH on

the growth of *C. botulinum* in canned tomatoes, pineapple, pears and figs, together with an evaluation of these data by the Food and Drug Administration, have been placed on display for public review at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

If cultural varieties of a product have a pH greater than 4.6, such varieties will be exempt by this proposed regulation from Part 128b only if the canning firm has adequate data on record to show that the maximum pH of its raw product before acidification never exceeds 4.6. If the pH of the raw product exceeds 4.6 and the product is acidified, it will be covered by proposed Part 128g rather than by Part 128b.

The definition of "scheduled process" is modified to require that it be equivalent to the process established by a competent processing authority to achieve commercial sterility. Some have asked that the qualifications of a competent processing authority be described. In the Commissioner's opinion the technology for establishing an adequate process for a low-acid canned food is complex and generally learned only by practical experience in addition to formal training. A competent processing authority must fully appreciate all the factors affecting the rate of heat penetration and must understand the need to use all features of food microbiology including the microbiology of canning. Some special staff members of the following organizations possess such a competence: Laboratories of container suppliers, canning industry trade associations, universities, canning firms, consultants, and government.

2. *Section 128b.3.* Sometimes low-acid foods are acidified to a pH higher than 4.6, and the acidification is used in conjunction with a thermal process. Such foods will continue to be regulated under Part 128b. Paragraph (e) is modified to require that the equilibrium pH of the finished product is as specified in the scheduled process and that the provisions of proposed Part 128g apply to the control of acidification.

When control of water activity is used in conjunction with the thermal process to prevent growth of spore-forming microorganisms not destroyed by the thermal process, the control of food composition and other food properties is critical to the safety of the food. Proposed paragraph (f) is added to this section to assure that all critical factors in the scheduled process are controlled and that limits set in the scheduled process are not exceeded.

3. *Section 128b.4.* This section on the establishment of thermal processes is amended to codify the Commissioner's intention that procedures for calculation of thermal processes follow those recognized by competent processing authorities.

4. *Section 128b.5.* Paragraph (b) concerning the marking of retort baskets or containers is expanded to require a system of traffic control and to require that heat sensitive indicators be visually checked. This amendment provides a further precaution to lessen opportunities for products to bypass the retort.

Paragraph (c) is expanded to require that, when water is present in a retort during filling or processing, the water must not lower the initial temperature of the contents of the containers below that specified in the scheduled process.

New paragraphs are added to: recommend that times on recording temperature charts agree with the actual time of day as reflected on the written processing records; require that steam supply be adequate; and require that evidence of the adequacy of air removal be recorded and filed when mufflers are used.

5. *Section 128b.6.* The current regulation in one place requires the mercury-in-glass thermometer to have a temperature range of not more than 100° F on a scale at least 7 inches in length, while in another place it requires a temperature range of not more than 150° F on a scale at least 9 inches in length. For consistency, the Commissioner proposes to change the thermometer requirement to require divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch. This amendment will allow the use of some commercially produced thermometers that are fractionally out of compliance with the current regulation. The proposed regulation recommends keeping records of test results and the date of testing for thermometer accuracy.

Since it is essential that the recording device register no higher than the mercury-in-glass thermometer, the requirement that the recording device be adjusted to agree within 1° F of the mercury-in-glass thermometer is to be amended to read: "The temperature chart shall be adjusted as nearly as possible to agree with, but shall in no event be higher than, the known accurate mercury-in-glass thermometer during the processing time."

The current regulation states that each chart shall have a working scale of not more than 50° F per inch. Many manufacturers now produce recording instruments with charts that have a working scale up to 55° F per inch. The Commissioner, not wishing to add an unnecessary expense to the manufacturer to modify such instruments, proposes to change the requirement from 50° F to 55° F per inch.

The mandatory use of the pressure gage is dropped because it serves no essential function in the thermal processing of low-acid foods.

The paragraph concerning bleeders is amended to clarify the position of bleeders on horizontal still retorts and to allow alternate locations of bleeders, provided there is positive evidence of adequate venting of air.

Paragraph (a)(11) is added to require that retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

"Venting" is the term used to identify that portion of the retorting cycle during which air is flushed from the retort with steam. Retort venting is a critical operation, which is an essential element in the safe processing of low-acid canned foods. Field inspection results indicate that some retort operators either do not understand its purpose or they fail to appreciate its importance. Consequently, the codified language on venting has been reorganized for clarification. In establishing retort venting schedules, it is essential that the principles of venting be taken into account. Pockets of air entrapped during retoring insulate cans from steam and retard heat transfer, resulting in sporadic low level spoilage and posing a potential public health hazard. All established processes are valid only if an atmosphere of pure steam is achieved and maintained. Complete removal of air from the retort is achieved by the free flow of a high volume of steam through the retort chamber. Anything that interferes with this flow of steam prolongs the time necessary to remove entrapped air.

Obviously, an ample supply of steam at all times is basic. To reduce costs, conserve energy, and minimize product overcooking, venting schedules should be established by running heat distribution tests using multiple thermocouples scattered through the retort load under the operating conditions of each product and type of equipment. Once established, the venting schedules must be followed rigidly, and if operating conditions are changed, the venting schedule must be redetermined by heat distribution tests. Factors to be kept in mind are: (a) Cold retorts vent more slowly than hot retorts because initially steam condenses rather than flushing air from the retort; (b) likewise, a retort loaded with cold cans vents more slowly than one loaded with hot cans; (c) it is more difficult to remove air from among small cans than from among large cans because the steam flow is impeded due to a larger number of potential "traps"; (d) stacked cans hold air pockets better than do jumbled cans; (e) divider plates between layers of cans in a crate retard venting, necessitating special venting schedules; (f) inadequately perforated crates prolong the venting period required to achieve air removal; and (g) a globe valve on the discharge (vent) line retards steam flow, as compared to a gate valve of the same size, and thus reduces venting efficiency. Once the air is removed from the retort and the temperature has been brought up to the temperature specified in the scheduled process, the vent line is closed but bleeders must be left open.

Bleeders serve three purposes: (a) On pockets containing thermometer bulbs or temperature sensors for controllers or recorders they ensure that the temperature of the steam in the pocket is representative of the steam temperature in the

retort; (b) they prevent the accumulation of air which is carried into the retort with the steam supply; and (c) they promote steam circulation within the body of the retort. On some types of retorts bleeders must also be used to prevent the accumulation of condensate. Proper retort venting is an essential to good processing as is accurate control of time and temperature.

The paragraph concerning still retorts used for processing in water is expanded to require that the operator check and record the water level and that heat distribution tests be made and recorded to show the adequacy of air or water circulation.

Paragraphs relating to continuous agitating retorts are enlarged to require that heat distribution data be kept on file and that a scheduled still process be made available to the operator for use in an emergency.

A new paragraph requiring flow diversion valves in aseptic processing is added because the Commissioner believes it to be essential to have a flow diversion valve where liquid products are being aseptically processed. The incubation of samples of aseptically processed foods is no longer mandatory.

A new paragraph (i) is added to specify more clearly the requirements for processes wherein water activity control is used in conjunction with the thermal process.

The present paragraph (i) on "new" systems is deleted and a new paragraph (j) on "other" systems is added.

A new paragraph (k) is added to allow alternative processing and control systems when the processor has the express written approval of the Food and Drug Administration.

6. *Section 128b.7.* The paragraph on the visual examination of can seams is expanded to designate specifically what is to be examined during the visual examination of the top seam of a can.

Thickness in can seaming is critical. Therefore, its measurement is now to be required.

A paragraph relating to the closures of glass containers is added because, although the current regulation does not explicitly mention glass containers, its provisions apply to such containers.

The heading of the section on "cooling" is changed to "cooling water." The Commissioner proposes therein to require the chlorination of water for cooling canals and for recirculated water supplies to ensure against contamination.

7. *Section 128b.8.* One new paragraph is proposed. It would require that records be kept to identify the initial distribution of the finished product.

8. *Section 128b.9.* The proposed amendment requires the maintenance of a separate file for all process deviations where the minimum requirements set by the scheduled process are not satisfied. This will enable the processor as well as an FDA investigator to ascertain readily which product may have been underprocessed.

Finally, a number of clarifying editorial changes are proposed.

Accordingly, the Commissioner of Food and Drugs proposes to revise the good manufacturing practice regulation for the manufacture and processing of thermally processed low-acid foods packaged in hermetically sealed containers.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. The Commissioner has also carefully considered the inflation impact of the proposed regulation as required by Executive Order 11821, OMB Circular A–107, and interim guidelines issued April 1, 1975 by the Department of Health, Education, and Welfare, and no major inflation impact has been found. Copies of the FDA environmental and inflation impact assessments are on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by revising Part 128b to read as follows:

Sec.

128b.1 Definitions.
128b.2 Current good manufacturing practice.
128b.3 Product preparation.
128b.4 Establishing scheduled processes.
128b.5 Operations in the thermal processing room.
128b.6 Equipment and procedures.
128b.7 Containers.
128b.8 Processing and production records.
128b.9 Deviations in processing, venting, or control of critical factors.
128b.10 Personnel.

AUTHORITY: Secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a)).

§ 128b.1 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Aseptic processing and packaging" means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) "Bleeders" means openings used to remove air that enters with steam from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) "Coming-up-time" means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) "Commercial processor" shall include any person engaged in commercial, custom, and so-called sportsman processing or institutional (church, school, penal, or other organization) processing of food, including pet food.

(e) "Commercial sterility" of termally processed food means the condition achieved by application of heat which renders such food free of viable forms of microorganisms having public health significance, as well as viable forms of microorganisms of nonhealth significance capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution. "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment which renders such equipment and containers free of viable forms of microorganisms having public health significance as well as viable forms of microorganisms of nonhealth significance capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) "Critical factor" means any property, characteristic, condition, aspect or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility.

(g) "Flame sterilizer" means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, with impinging gas flames to achieve sterilization temperatures. A holding period in a heated section may follow the initial heating period.

(h) "Headspace, gross" is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

(i) "Headspace, net" of a container is the vertical distance between the level of the product (generally the liquid surface) in the upright rigid container and the inside surface of the lid.

(j) "Hermetically sealed container" means a container which is designed and intended to be secure against the entry of microorganisms and to thereby maintain the commercial sterility of its contents after processing.

(k) "Incubation" means the holding of a sample(s) at a specified temperature for a specified period of time for the purpose of permitting or stimulating the growth of microorganisms.

(l) "Initial temperature" means the average temperature of the contents of the coldest container to be processed at the time the thermal processing cycle begins, as determined after thorough stirring or shaking of the filled and sealed container.

(m) "Lot" means that amount of a product produced during a period of time indicated by a specific code.

(n) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH value greater than 4.6 and a water activity (a_w) greater than 0.85.

(o) "Minimum thermal process" means the application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.

(p) "Operating process" means the process selected by the processor that equals or exceeds the minimum requirements set forth in the scheduled process.

(q) "Retort" means any closed vessel or other equipment used for the thermal processing of foods.

(r) "Scheduled process" means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. This process may be in excess of that necessary to ensure destruction of microorganisms of public health significance, and shall be at least equivalent to the process established by a competent processing authority to achieve commercial sterility.

(s) "Shall" and "should." As used in this part, "shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(t) "Vacuum-packed products" means those products that are sealed in a container under the vacuum specified in the scheduled process, the maintenance of which vacuum is critical to the adequacy of the scheduled process.

(u) "Vents" means openings controlled by gate, plug cock, or other adequate valves used for the elimination of air during the venting period.

(v) "Water activity" (a_w) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 128b.2 Current good manufacturing practice.

The criteria in §§ 128b.3 through 128b.10 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

§ 12b8.3 Product preparation.

(a) The processor shall assure that raw materials and ingredients susceptible to microbiological contamination are suitable for use in processing low-acid foods prior to their use in such foods. This may be accomplished by examining such raw materials and ingredients for microbiological condition, receiving them under a supplier's guarantee that they are suitable for use, or by other acceptable means.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. Where the blanched food product is washed prior to filling, potable water should be used.

(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.

(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. This may be done by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(e) When the maintenance of pH of a normally low-acid food is a basis for a scheduled process, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process. The methodology described in § 128g.8 of this chapter shall be used.

(f) When the scheduled process sets forth critical factors such as water activity control to prevent the growth of microorganisms not destroyed by the thermal process, the factors shall be carefully controlled to ensure that the limits established in the scheduled process are not exceeded.

§ 128b.4 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors which may affect the scheduled process e.g., minimum headspace, consistency, maximum fill in or drained weight, a_w, etc., shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, where necessary, but not be limited to microbial thermal death time data, process calculations based on product heat penetration data, and inoculated packs. Calculation shall be performed according to procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for confirmation of the scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial production runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.

§ 128b.5 Operations in the thermal processing room.

(a) Operating and scheduled processes or both and retort venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or shall be made readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration.

(b) A system for product traffic control in the retort room shall be established to prevent unretorted products from bypassing the retort process. Each retort basket, truck, car or crate used to hold containers in a retort, or one or more containers therein, shall, if it contains any retorted food product be plainly and conspicuously marked with a heat sensitive indicator, or by other effective means which will visually indicate to thermal processing personnel units which have been retorted. A visual check shall be perfofmed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting for all retort baskets, trucks, cars or crates to ensure that each unit of product has been retorted. A written record of these checks should be made.

(c) The initial temperature of the contents of the containers to be processed shall be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process. For those operations which use water during the filling of the retort or during processing, provision shall be made to ensure that the water will not, prior to the start of each thermal process, lower the temperature specified in the scheduled process.

(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time specified in the scheduled process is achieved. Pocket or wrist watches or digital clocks shall not be considered satisfactory for timing purposes.

(e) Clock times on recording temperature charts should agree with the times on the written processing records.

(f) The steam supply to the thermal processing system shall be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands of steam by the plant.

(g) If mufflers are used on bleeders or vent systems, evidence that the bleeders or vents are operated in a manner that does not significantly impede the removal of air shall be kept on file. This may be in the form of heat distribution data or other satisfactory evidence.

§ 128b.6 Equipment and procedures.

(a) *Equipment and procedures for pressure processing in steam in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer which shall have divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy checks which specify date, standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attracted to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and shall be equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each still retort. Temperature recording devices shall have graduations that do not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shal be adjusted as nearly as possible to agree with, but shall in no event be higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a 1/16 inch or larger bleeder which emits steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry, air, which should be supplied to the retort controllers from a system that is separate from the air supply to the rest of the plant.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.

(6) *Crate supports.* A bottom crate support shall be employed in vertical still retorts. Baffle plates shall not be used in the bottom of still retorts.

(7) *Steam spreaders.* Horizontal still retorts shall be equipped with steam spreaders that extend along the bottom for the length of the retort; the perforations should be along the top 90° of this pipe, that is, within 45° on either side of the top center. Horizontal still retorts over 30 feet long should have two steam inlets connected to the spreader. In vertical still retorts the steam spreaders, if used, should be perforated along the top or sides of the pipe. The number of perforations in spreaders for horizontal still retorts should be such that the total cross-sectional area of the perforations is equal to 1½ to 2 times the cross-sectional area of the smallest steam inlet line.

(8) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the coming-up-time. For horizontal still retorts, bleeders shall be located within approximately 1 foot of each end of the shell of the retort; additional bleeders shall be located not more than 8 feet apart along the top. Bleeders may be more than 1 foot from the end of the shell of the retort provided that there is evidence in the form of heat distribution data that they accomplish adequate venting of air. Verical retorts shall have at least one bleeder opening located in that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

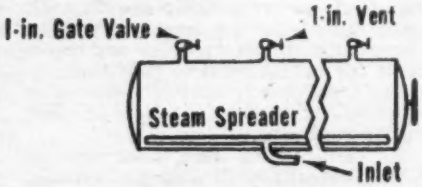
(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If dividers are used between the layers of containers, they should be perforated as above. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance therewith.

(10) *Air valves.* Retorts using air for pressure cooling shall be equipped with a suitable valve to prevent air leakage into the retort during processing.

(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.

(12) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or other adequate type valve. The retort manifold shall be of a size such that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached. Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts are given in paragraphs (a) (12) (i) (*a*) through (*d*) and (ii) (*a*) and (*b*) of this section.

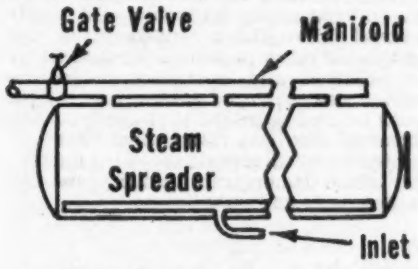
(i) *Venting horizontal retorts.* (*a*) Venting through multiple 1-inch vents discharging directly to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length, equipped with a gate or plub cock valve and discharging to atmosphere; end vents not more than 2½ feet from ends of retort.

Venting method. Vent valves should be wide open for at least 5 minutes and to at least 225° F., or at least 7 minutes and to at least 220° F.

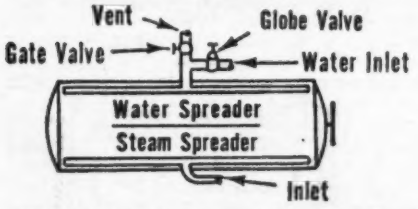
(b) Venting through multiple 1-inch vents discharging through a manifold to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length; end vents not over 2½ feet from ends of retort; size of manifold—for retorts less than 15 feet in length, 2½ inches; for retorts 15 feet and over in length, 3 inches.

Venting method. Manifold vent gate or plub cock valve should be wide open for at least 6 minutes and to at least 225° F, or for at least 8 minutes and to at least 220° F.

(c) Venting through water spreaders.

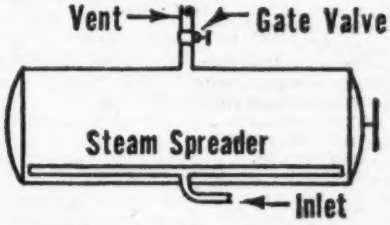


Size of water inlet, vent pipe, and vent valve. For retorts less than 15 feet in length, 2 inches; for retorts 15 feet and over in length, 2½ inches.

Size of water spreader. For retorts less than 15 feet in length, 1½ inches; for retorts 15 feet and over in length, 2 inches.

Venting method. Water spreader vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 225° F, or for at least 7 minutes and to at least 220° F.

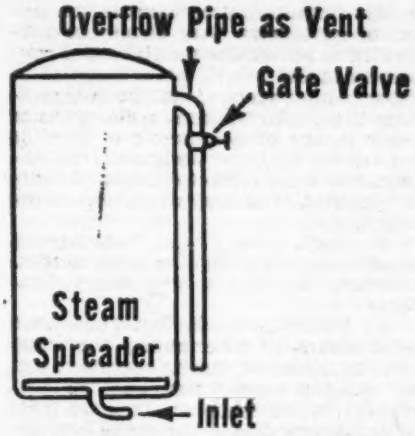
(d) Venting through a single 2½-inch top vent (for retorts not exceeding 15 feet in length).



Specifications: A 2½-inch vent equipped with a 2½-inch gate or plug cock valve and located within 2 feet of the center of the retort.

Venting method: Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220° F.

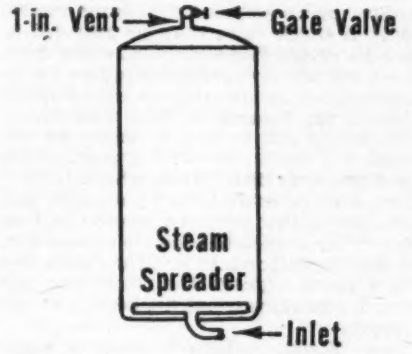
(ii) *Venting vertical retorts.* (a) Venting through a 1½-inch overflow.



Specifications. A 1½-inch overflow pipe equipped with a 1½-inch gate or plug cock valve and with not more than 6 feet of 1½-inch pipe beyond the valve before break to the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218° F, or for at least 5 minutes and to at least 215° F.

(b) Venting through a single 1-inch side or top vent.



Specifications. A 1-inch vent in lid or top side, equipped with a 1-inch gate or plug cock valve and discharging directly into the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 230° F or for at least 7 minutes and to at least 220° F.

(iii) Other installations and operating procedures which deviate from the above specifications may be used provided that there is evidence in the form of heat distribution data, which shall be kept on file, that they accomplish adequate venting of air.

(13) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) Where maximum fill in or drained weight is specified in the scheduled process it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum, in vacuum-packed products, shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) Where the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(b) *Equipment and procedures for pressure processing in water in still retorts.*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer which shall have divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently if necessary to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date when it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts this entry should be made in the side at the center, and the thermometer bulbs shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the thermometer bulbs shall extend directly into the water a minimum of at least 2 inches without a separable well or sleeve. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each still retort. Temperature recording devices shall have graduations that do not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted so as nearly as possible to agree with, but shall in no event be no higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjust-

ment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adustments, are satisfactory means for preventing unauthorized changes. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The recording thermometer bulb should be located adacent to the bulb of the mercury-in-glass thermometer except in the case of a vertical retort equipped with a combination recorder-controller. In such vertical retorts the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts the temperature recorder-control bulb shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement upon the control bulb. Air-operated temperature controllers should have adequate filter systems to assure a supply of clean, dry air, which should be supplied to the retort controllers from a system that is separate from the air supplied to the rest of the plant.

(3) *Pressure gages.* (i) Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 lbs. or less.

(ii) Each retort should have an adjustable pressure relief, or control valve of a capacity sufficient to prevent an undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Steam introduction.* The distribution of steam in the bottom of the retort shall be accomplished in a manner adequate to provide uniform heat distribution throughout the retort. In vertical retorts, uniform steam distribution can be achieved by any of several methods. In horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.

(6) *Crate supports.* A bottom crate support shall be employed in vertical still retorts. Baffle plates shall not be used in the bottom of the retort. Centering guides should be installed so as to ensure that there is about a 1½-inches clearance between the side wall of the crate and the retort wall.

(7) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If divider plates are used between the layers of containers, they should be perforated as above. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance therewith. Dividers, racks, trays or other means of positioning of flexibile containers shall be designed and employed to asure even circulation of heating medium around all containers in the retort.

(8) *Drain valve.* A nonclogging, water-tight valve shall be used. Screens should be installed over all drain openings.

(9) *Water level indicator.* There shall be a means of determining the water level in the retort during operation, e.g., by using a gage water glass or petcock(s). Water shall cover the top layer of containers during the entire coming-up-time and processing periods and should cover the top layer of containers during the cooling periods. The operator shall check and record the water level at intervals sufficient to ensure its adequacy.

(10)(i) *Air supply and controls.* In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system. Air or water circulation shall be maintained continuously during the coming-up-time and during processing and cooling periods; the adequacy of the air or water circulation for uniform heat distribution within the retort shall be established by a competent processing authority and records kept on file; if air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

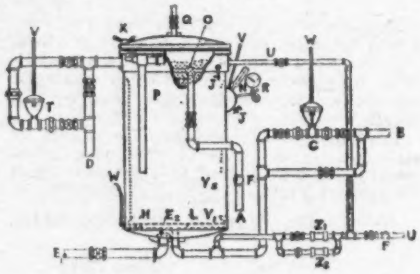
(ii) *Water circulation.* When a water circulating system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed and should have an aggregate area not greater than the cross section area of the outlet line from the pump. The suction outlets should be protected with nonclogging screens to keep debris from entering the circulating system. The pump shall be equipped with a pilot light or other signaling device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternative methods for circulation of water in the retort may be used when established as adequate for even heat distribution by a competent authority.

(11) *Cooling water supply.* In vertical retorts the cooling water should be introduced at the top of the retort between the water and container levels; in horizontal retorts the cooling water should be introduced into the suction side of the pump. A check valve should be inincluded in the cooling water line.

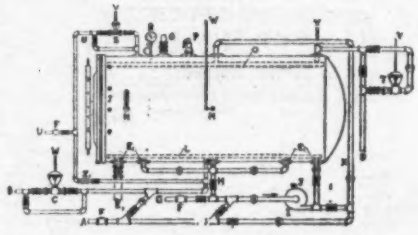
(12) *Retort headspace.* The headspace necessary to control the air pressure should be maintained between the water level and the top of the retort shell.

(13) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the diagrams below in this paragraph. Other installation and operating procedures which deviate from these arrangements may be used, provided that the firm shall have on file heat distribution data collected by a competent processing authority which demonstrate that the heat distribution is adequate.

Vertical Retorts



Horizontal Retorts



LEGEND FOR VERTICAL AND HORIZONTAL STILL RETORTS

A—Water line.
B—Steam line.
C—Temperature control.
D—Overflow line.
E_1—Drain line.
E_2—Screens.
F—Check valves.
G—Line from hot water storage.
H—Suction line and manifold.
I—Circulating pump.
J—Petcocks.
K—Recirculating line.
L—Steam distributor.
M—Temperature controller bulb.
N—Thermometer.
O—Water spreader.
P—Safety valve.
Q—Vent valve for steam processing.
R—Pressure gage.
S—Inlet air control.
T—Pressure control.
U—Air line.
V—To pressure control instrument.
W—To temperature control instrument.
X—Wing nuts.
Y_1—Crate support.
Y_2—Crate guides.
Z—Constant flow orifice valve.
Z_1—Constant flow orifice valve used during come-up.
Z_2—Constant flow orifice valve used during cook.

(14) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. (i) Where maximum fill in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(iv) Where the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.

(c) *Equipment and procedures for pressure processing in steam in continuous agitating retorts.*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer which shall have divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently if necessary to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and shall be equipped with a ⅛-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb.

The bleeders for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort. Temperature recording devices shall have graduations that do not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted as nearly as possible to agree with, but shall in no event be higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, are satisfactory means of preventing unauthorized changes. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to assure a supply of clean, dry air, which should be supplied to the retort controllers from a system that is separate from the air supply to the rest of the plant.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is mechanically maintained so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the coming-up time. Bleeders shall be located within approximately 1 foot of the intake valve and the exhaust valve; additional bleeders shall be located not more than 8 feet apart along the top of the retort. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. This should be done at intervals of not more than 15 minutes. A record of such checks should be kept to show that it is functioning properly.

(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. Heat distribution data, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time a speed change is made, and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided.

(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall either be operated as a still retort, with all containers being given a full still retort process before the retort is cooled, or the retort shall be cooled promptly and all containers shall be either reprocessed, repacked and reprocessed, or discarded. A scheduled still process to be used in such emergency shall be made readily available to the retort operator.

(i) Any containers in the retort intake valve of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.

(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort at the time of stopping and cooling shall be entered on the production records.

(iii) A complete record of handling all such emergencies shall be made a part of a process deviation file as required under § 128b.9.

(9) *Temperature drop.* If the temperature of the continuous retort drops below the temperature specified in the scheduled process while containers are in the retort, the retort reel shall be stopped promptly. An automatic device should be used to stop the reel when the temperature drops below the specified process temperature. Before the reel is restarted, all containers in the retort shall be given a complete scheduled still retort process if the temperature drop was 10° F or more below the specified temperature, or alternatively, container entry to the retort shall be stopped and the reel shall be restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or discarded. Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chap-

ter. If the alternative procedure of emptying the retort is followed, the subsequent handling methods used for the containers in the retort at the time of the temperature drop shall be entered on the production records. If the temperature drop was less than 10° F, a scheduled authorized emergency still process approved by a qualified person(s) having expert knowledge of thermal processing requirements may be used before restarting the retort reel. Alternatively, container entry to the retort shall be stopped and an authorized emergency agitating process may be used before container entry to the retort is restarted. When emergency procedures are utilized, no containers shall enter the retort and the process and procedures used shall be noted on the production records.

(10) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to insure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum fill in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(d) *Equipment and procedures for pressure processing in steam in discontinuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer which shall have divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently if necessary to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch-diameter opening, and shall be equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort. Temperature recording devices shall have graduations that do not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted as nearly as possible to agree with, but shall in no event be higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period. Air-operated temperature controllers should have adequate filter systems to assure a supply of clean, dry air, which should be supplied to the retort controllers from a system that is separate from the air supplied to the rest of the plant.

(3) *Pressure gages.* Each retort should be equipped with a pressure gage, which should be graduated in divisions of 2 pounds or less.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is mechanically maintained so that it operates satisfactorily.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the coming-up-time. Bleeders shall be located within approximately 1 foot of each end of the shell of the retort; bleeders may be more than 1 foot from the end of the shell of the retort provided that there is evidence in the form of heat distribution data that they accomplish adequate venting of air; additional bleeders shall be located not more than 8 feet apart along the top of the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to ensure removal of condensate. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Venting and condensate removal.* The air in each retort shall be removed before processing is started. Heat distribution data which demonstrates that adequate venting is achieved shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for continuing drainage of condensate during the retort operation.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The rotational speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided.

(8) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum fill in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(e) *Equipment and procedures for pressure processing in water in discontinuous agitating retorts*—(1) *Indicating*

mercury-in-glass thermometer. Each retort shall be equipped with at least one mercury-in-glass thermometer which shall have divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently if necessary to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device*. There shall be an accurate temperature recording device for each retort. Temperature recording devices shall have graduations that do not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted as nearly as possible to agree with, but shall in no event be higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Air-operated temperature controllers should have adequate filter systems to assure a supply of clean dry air, which should be supplied to the retort controllers from a system that is separate from the air supply to the rest of the plant.

(3) *Pressure gages*. Each retort should be equipped with a pressure gage which should be graduated in divisions of 2 pounds of less.

(4) *Steam controller*. Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Retort speed timing*. The rotational speed of the retort shall be specified in the scheduled process. The rotational speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided.

(6) *Air supply and controls*. Means shall be provided for introducing compressed air at the proper pressure and rate, which shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.

(7) *Critical factors*. Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum fill in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(f) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—(1) *Indicating mercury-in-glass thermometer*. Each retort shall be equipped with at least one mercury-in-glass thermometer which shall have divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently if necessary to ensure their accuracy. Records of thermometer accuracy checks which specify date, standard used, method used and person performing the test should be maintained. Each thermometer should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort. Thermometers shall be installed where they can be accurately and easily read. The thermometer shall be located in the steam dome near the steam-water interface. Where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a mercury-in-glass thermometer shall be located in each hydrostatic water leg in a position near the bottom automatic recorder. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device*. There shall be an accurate temperature recording device for each retort. Temperature recording devices shall have graduations that do not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the processing temperature. The temperature chart shall be adjusted as nearly as possible to agree with, but shall in no event be no higher than, the known accurate mercury-in-glass thermometer during the process time. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments are satisfactory means for preventing unauthorized changes. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the steam dome or in a well attached to the dome. Temperature recorder bulb wells shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the entire processing period. Additional temperature recorder bulbs shall be installed in the hydrostatic water legs if the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs. Air-operated temperature controllers should have adequate filter systems to assure a supply of clean dry air, which should be supplied to the retort controllers from a system that is separate from the air supply to the rest of the plant.

(3) *Pressure gages*. Each retort should be equipped with a pressure gage which should be graduated in divisions of 2 pounds or less.

(4) *Recording of temperatures*. Temperatures indicated by the mercury-in-glass thermometer or thermometers shall be entered on a suitable form during processing operations. Temperatures shall be recorded by an accurate automatic recorder or recorders at the following points:

(i) In the steam chamber between the steam-water interface and the lowest container position.

(ii) Near the top and the bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the legs.

(5) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer. A steam controller activated by the steam pressure of the retort is acceptable if it is mechanically maintained so that it operates satisfactorily.

(6) *Venting.* Before the start of processing operations, the retort steam chamber or chambers shall be vented to ensure removal of air.

(7) *Bleeders.* Bleeder openings (¼ inch or larger shall be located at the end of the steam chamber or chambers opposite from the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the coming-up-time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(8) *Retort speed.* The speed of the container conveyor chain shall be specified in the scheduled process and shall be determined and recorded at the start of processing and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified. The speed should be determined and recorded every 4 hours. An automatic device should be used to stop the chain when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided.

(9) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

(i) Where maximum fill in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Minimum closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(g) *Aseptic processing and packaging systems*—(1) *Product sterilizer*—(i) *Equipment*—(a) *Temperature indicating device.* Each product sterilizer shall be equipped with at least one mercury-in-glass thermometer or an equivalent temperature-indicating device, such as a thermocouple-recorder. Mercury-in-glass thermometers shall have divisions that are easily readable to 1° F and whose temperature range does not exceed 17° F per inch of graduated scale. Thermometers and temperature indicating devices shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a month thereafter or more frequently if necessary to ensure their accuracy. Records of accuracy checks which specify date, standard used, method used and person performing the test should be maintained. Each thermometer and temperature indicating device should have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy. A thermometer that has a divided mercury column or that cannot be adjusted to essential agreement with the standard shall be repaired or replaced. Thermometers and temperature indicating devices shall be installed where they can be accurately and easily read. The temperature indicating device shall be the reference instrument for indicating the processing temperature.

(b) *Temperature recording device.* There shall be an accurate temperature recording device on each product presterilizer. The temperature sensor shall be located in the presterilized product at the holding tube outlet between the holding tube and the inlet of the cooler. The device shall be installed in the product at the holding tube outlet between the holding tube and the inlet to the cooler. Temperature recording devices shall have graduations that do not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 55° F per inch within a range of 20° F of the desired product sterilization temperature. The temperature chart shall be adjusted as nearly as possible to agree with, but shall in no event be higher than, a known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes.

(c) *Temperature recorder-controller.* An accurate temperature recorder-controller shall be located in the product sterilizer at the final heater outlet. It shall be capable of assuring that the desired product sterilization temperature is maintained. The chart graduations shall not exceed 2° F within a range of 10° F of the desired product sterilization temperature. Air-operated temperature controllers should have adequate filter systems to assure a supply of clean, dry air. The air should be applied to the retort controllers from a system that is separate from the rest of the plant.

(d) *Product-to-product regenerators.* Where a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to ensure that any leakage in the regenerator will be from the sterilized product into the unsterilized product.

(e) *Differential pressure recorder-controller.* Where a product-to-product regenerator is used, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 2 pounds per square inch on a working scale of not more than 20 pounds per square inch per inch. The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation and at least once every 3 months of operation thereafter or more frequently if necessary to ensure its accuracy. One pressure sensor shall be installed at the sterilized product regenerator outlet, and the other pressure sensor shall be installed at the unsterilized product regenerator inlet.

(f) *Metering pump.* A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized speed changes shall be provided.

(g) *Product holding tube.* The product sterilizing holding tube shall be designed to give continuous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it shall be sloped upward at least 0.25 inch per foot.

(h) *Flow diversion valve.* A flow diversion valve shall be installed between the cooler and filler and the system controlled so as to divert product flow away from the filler whenever the temperature of the product in the holding tube falls below the sterilization temperature specified in the scheduled process, except that a flow diversion valve need not be installed when products with discrete particles are being processed.

(ii) *Operation*—(a) *Startup.* Prior to the start of aseptic processing operations, the product sterilizer shall be brought to a condition of commercial sterility.

(b) *Temperature drop in product sterilizing holding tube.* When product temperature in the holding tube drops below the temperature specified in the scheduled process, the product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before flow is resumed to the filler.

(c) *Loss of proper pressures in the regenerator.* Where a regenerator is used the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 1 pound per square inch greater than the pressure of unsterilized product in the regenerator. Product flow to the filler shall not be resumed until the cause of the improper pressure relationships in the regenerator has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

(d) *Records.* Readings at the following points shall be observed and recorded

at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process: Temperature indicating device in holding tube outlet; temperature recorder in holding tube outlet; temperature recorder-controller at final heater outlet; differential pressure recorder-controller, if a product-to-product regenerator is used; and product flow rate as established by the metering pump or as determined by filling and closing rates. Such measurements and recordings should be made at intervals not to exceed 1 hour.

(2) *Container sterilizing, filling, and closing operation*—(i) *Equipment*—(a) *Recording device.* The container and closure sterilization system and product filling and closing system shall be instrumented to demonstrate that the required sterilization is being accomplished continuously. Automatic recording devices shall be used to record, where applicable, the sterilization media flow rates or temperatures or both. Where a batch system is used for container sterilization, the sterilization conditions shall be recorded.

(b) *Timing method(s).* A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment specified in the scheduled process, or to control the sterilization cycle at the rate specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided.

(ii) *Operation*—(a) *Startup.* Prior to the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

(b) *Loss of sterility.* In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

(c) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates and/or temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.

(3) *Incubation.* Incubation tests should be conducted on a representative sample of containers of product from each code; records of the tests should be maintained.

(4) *Critical factors.* When a critical factor is specified in the scheduled process, it shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factor is within the limits specified in the scheduled process. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(h) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing changes in flame intensity and unauthorized speed changes on the conveyor shall be provided. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the entry and at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(i) *Process interruption.* In the event of process interruption wherein the temperature of the product may have dropped, an authorized, scheduled emergency plan approved by a qualified person having expert knowledge of the process requirements may be used.

(2) *Critical factors.* When a critical factor is specified in the scheduled process, it shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factor is within the limits specified in the scheduled process.

(i) *Equipment and procedures for thermal processing of foods wherein critical factors such as water activity are used in conjunction with thermal processing.* The methods and controls used for the manufacture, processing, and packing of such foods shall be as established in the scheduled process and shall be operated or administered in a manner adequate to ensure that the product is safe. The time and temperature of processing and other critical factors specified in the scheduled process shall be measured with instruments having the accuracy and dependability adequate to assure that the requirements of the scheduled process are met. All measurements shall be made and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.

(j) *Other systems.* All systems, whether or not specifically mentioned in this part, for the thermal processing of low-acid foods in hermetically sealed containers shall conform to the applicable requirements of this part and the methods and controls used for the manufacture, processing and packing of such foods shall be as established in the scheduled process and shall be operated or administered in a manner adequate to ensure that commercial sterility is achieved. Critical factors specified in the scheduled process shall be measured and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.

(k) *Alternative processing and control systems.* In addition to the procedures prescribed above, systems and equipment which deviate from the specifications of this section may be used with the express written approval of the Food and Drug Administration.

§ 128b.7 Containers.

(a) *Closures.* Regular observations shall be maintained during production runs for gross closure defects. Any such defects shall be recorded and corrective action taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used and shall record his observations. For double-seam cans, each can should be examined for cut-over or sharpness, skidding or dead-heading, false seam, droop at the cross-over or lap, and condition of inside of countersink wall for evidence of broken chuck. Such measurements and recordings should be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closure machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. Where irregularities are found, the corrective action shall be recorded.

(1) Teardown examinations for double seam cans shall be performed by a qualified individual and the results therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seaming station to ensure maintenance of seam integrity. Such examinations and recordings should be made at intervals not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective action taken, if any, shall be noted.

(i) Required and optional can seam measurements:

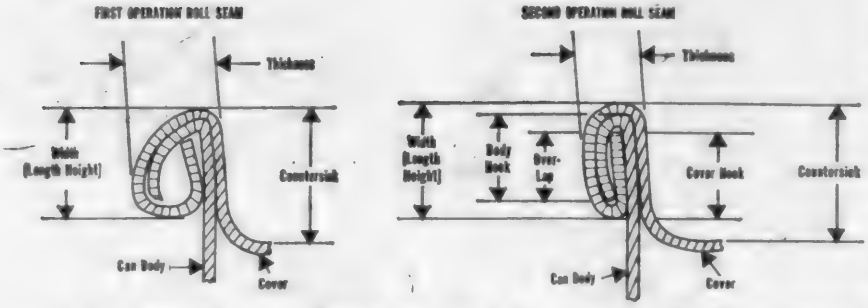
(a) Micrometer measurement system:

Required	*Optional*
Cover hook.	Overlap (by calculation).
Body hook.	Countersink.
Width (length, height).	
Tightness (observation for wrinkle).	
Thickness.	

(b) Seam scope or projector:

Required	*Optional*
Body hook.	Width (length, height).
Overlap.	Cover hook.
Tightness (observation for wrinkle).	Countersink.
Thickness.	

(c) Can double seam terminology:



. (1) *Cross-over:* The portion of a double seam at the lap.

(2) *Cut-over:* Sharp bend or break in the metal at the tip of the countersink.

(3) *Dead-head:* A seam which is incomplete due to chuck spinning in the countersink.

(4) *Droop:* Smooth projection of double seam below bottom of normal seam.

(5) *False seam:* A small seam breakdown where the cover hook and the body hook are not overlapped.

(6) *Lap:* Two thicknesses of material bonded together.

(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120° apart, excluding the side seam.

(iii) Overlap length can be calculated by the following formula:

The theoretical overlap length =
CH + BH + T − W where
CH = cover hook
BH = body hook
T = cover thickness, and
W = seam width (height, length)

(2) For glass containers with vacuum closures, capper efficiency shall be checked by a measurement of the cold water vacuum. This shall be done prior to actual filling operations, and the results shall be recorded.

(3) For closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b) *Cooling water.* Container cooling water shall be chlorinated as necessary for cooling canals and for recirculated water supplies so that there is a measurable free chlorine residual at the water discharge point of the container cooler. Other safe chemical or physical treatment which is equivalent to chlorination in its bactericidal effect may be used.

(c) *Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code which shall be permanently visible to the naked eye. Where the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, provided that the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: Intervals of 4 to 5 hours; personnel shift changes; or batches, provided the containers comprising such batch do not extend over a period of more than one personnel shift.

(d) *Postprocess handling.* Where cans are handled on belt conveyors, such conveyors should be so constructed as to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc. should be replaced with new nonporous material. All tracks and belts which come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. Automatic equipment used in handling filled containers should be so designed and operated in such a manner as to preserve the can seam or other container closure integrity.

§ 128b.8 Processing and production records.

(a) Processing and production information shall be entered at the time it is observed by the retort or processing system operator, or other designated person, on forms which shall include the product, the code number, the date, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the initial temperature, the actual processing time, the mercury-in-glass and recording thermometer readings, and other appropriate processing data. Closing machine vacuum (in vacuum-packed products), maximum fill in or drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

(1) *Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and temperature to which vented.

(2) *Agitating retorts.* Functioning of condensate bleeder; retort speed; and, where specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.

(3) *Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.

(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature indicating device and the temperature recorder; product temperature in the final heater outlet as indicated by the temperature recorder-controller; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate, as determined by the metering pump or by filling and closing rates; sterilization media flow rate or temperature or both; retention time of containers, and closures where applicable, in the sterilizing environment; and, where a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

(5) *Flame sterilizers.* Container conveyor speed; surface temperature at the beginning and at the end of the holding period; nature of container.

(6) *Foods wherein critical factors such as water activity are used in conjunction with thermal processing.* Product formulation, scheduled processes used including the thermal process, critical factors are results of a_w determinations.

(7) *Other and alternate systems.* Critical factors specified in the formulation of the product or in the scheduled process.

(b) Recording thermometer charts shall be identified by date, retort number and other data as necessary, so they can be correlated with the written record of lots processed. Each entry on the processing and production records shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and such retort or processing system operator or other designated person shall sign or initial each record form. Not later than 1 working day after the actual process, and prior to shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer.

(c) Written records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective ac-

tions taken. Records shall be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to assure that the containers are hermetically sealed.

(d) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for their intended use.

(e) Copies of all records provided for in this part, except those required under § 128b.4 establishing scheduled processes, shall be retained at the processing plant for a period of not less than 1 year, and at the processing plant or other reasonably accessible location for an additional 2 years. If, during the first year of the 3-year record retention period, the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.

§ 128b.9 Deviations in processing, venting, or control of critical factors.

Whenever any process is less than the scheduled process for any low-acid food or container system as disclosed from records by processor check or otherwise, the commercial processor of such low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, shall set aside that portion of the product involved for further evaluation as to any potential public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless such evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside either shall be fully reprocessed to render it commercially sterile or destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commercial sterility or after the determination that no significant potential for public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed. All process deviations involving a failure to satisfy the minimum requirements of the scheduled process shall be recorded and made the subject of a separate file detailing those deviations and the actions taken.

§ 128b.10 Personnel.

The operators of processing systems, retorts, aseptic processing and packaging systems and product formulating systems (including systems wherein water activity is used in conjunction with thermal processing) and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction appropriate to the preservation technology involved and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. This person shall supervise only in those areas for which a school approved by the Commissioner identifies him as having satisfactorily completed training.

Interested persons may, on or before September 21, 1976, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 2, 1976.

SHERWIN GARDNER,
Deputy Commissioner of Food and Drugs.

[FR Doc.76-21109 Filed 7-22-76;8:45 am]

[21 CFR Part 128g]

[Docket No. 75P-0334]

PICKLED, FERMENTED, AND ACIDIFIED FOODS

Good Manufacturing Practice

The Food and Drug Administration (FDA) proposes to establish a current good manufacturing practice regulation for pickled, fermented, and acidified foods that will provide processors of these foods with guidelines for the preparation of products that are free of adulteration and safe for human consumption. Interested parties have until September 21, 1976 to submit comments.

After consideration of all comments received in response to this proposal, a final regulation will be published in the FEDERAL REGISTER. The Commissioner proposes that the final regulation be effective 60 days after the date of publication.

The Pickle Packers International (PPI), Oak Park, IL 60174, an international trade association of pickle manufacturers, salters, and packers, has submitted a petition to establish a current good manufacturing practice regulation for the pickle industry. This petition is on display at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

FDA has reviewed this petition, has evaluated the conditions under which pickles and related products are manufactured and packaged for human consumption, and has decided to publish its own proposal for public comment. Because some products are prepared under insanitary conditions and under conditions that may endanger public health additional regulation is needed. Both the FDA and the PPI seek to improve the practices of the industry to ensure that all of these products are manufactured under sanitary conditions and are safe and wholesome.

During the years 1953 through 1958, FDA surveyed 49 pickle processing plants to assess sanitation and acceptability of processing practices. The methods for processing pickles that were used during the survey were about the same then as now. This survey covered 34 specific items in the processing of pickles. The most common problem in all areas inspected was the presence of insects. After completing the survey, FDA submitted appropriate recommendations for the control of insects and for improved sanitary practices for pickle fermentation tanks to the National Pickle Packers Association (now Pickle Packers International) for inclusion in their revised "Code of Sanitation" dated June 1, 1959. This code, which is still available to the industry, contains a sanitary code for pickle plant premises, including: control of rodents and insects; standards for equipment, manufacturing practices, methods of analysis, personnel, and maintenance; and sanitation of tank yards and salting stations.

The most critical factor in controlling growth of *Clostridium botulinum*, the primary public health problem in pickled, fermented, and acidified foods, as well as other types of pathogenic microorganisms in pickled and acidified food producs, is pH. Therefore, it is most important that a "safe pH" be achieved and maintained. The petition from the PPI defines a "safe pH" as 4.7 or less. The Commissioner of Food and Drugs believes that a "safe pH" is 4.6 or less. In § 128b.1(m) (21 CFR 128b.1(m)), dealing with thermally-processed low-acid foods packaged in hermetically sealed containers, a pH value of 4.6 or less is listed as the breakpoint between a low-acid and acid food. This breakpoint pH value is based on available scientific information on conditions under which bacteria of public health significance cannot grow or produce toxins. The PPI did not furnish supporting data or justify their belief that a maximum pH value of 4.7 is adequate for pickle products. The Commissioner invites comments and supporting data on this point.

A number of articles have been published concerning acidity and the growth of *C. botulinum*. Several references concern the acidification of pimientos, a normally low-acid food that is acidified to permit safe processing at a low temperature in order to make canned pimientos acceptable for sale. (Refs. 1 through 5). In such foodstuffs, where acidification or fermentation is relied upon to prevnt growth of *C. botulinum*, a maximum pH of 4.6 appears to provide an ample safety margin (Refs. 6, 7, and 8).

Because of the low water activity of the system, salt stock fermented pickles may be stored safely in a 10 percent salt solution until they are processed into finished pickles (Refs. 9, 10, and 11).

Fermentation and salting procedures are described in a number of publications (Refs. 12 through 15).

Between 1899 and 1964, there were 29 reported outbreaks of botulism in home-canned foods resulting in 101 illnesses and 55 deaths from home-canned pickled beets, peppers, pimientos and pickles (Ref. 16). Because botulinum toxin was found in these products, it is obvious that the products were not sufficiently acidified.

From January 1972 through December 1975, pickled, fermented, or acidified foods were involved in 4 seizures, 38 recalls, and the issuance of 20 letters to foreign processors stating that their products would no longer be allowed to enter the United States.

The four seizures included two for bacterial spoilage, one for label violations, and one for an excessive amount of tin in the product. Two of the recalls were due to botulinum poisoning that occurred in acidified foods commercially processed in the United States. As a result of these botulinum poisonings, eight people became ill—seven from peppers and one from marinated mushrooms. The peppers were canned in a plant lacking a pH meter and adequate thermometers and were not properly acidified. The mushrooms were not entirely immersed in the acidification bath prior to packing in oil and, consequently, some of them were not acidified. Of the 36 remaining recalls, 34 involved products (31 imported peppers and pimientos, 2 domestic peppers and 1 imported hearts of palm) which were not acidified to a pH of 4.6 or lower. The other two recalls involved filth in domestic pickles but did not involve insufficient acidification.

All of the processors involved in these actions appeared to lack an awareness of the importance of adhering to critical processing parameters to assure a safe product.

Information relating to the incidents described above has been placed on display for public review at the office of the Hearing Clerk, Food and Drug Administration.

Some products that purport to be pickles and have a pH above 4.6 are currently being marketed in hermetically sealed containers. Although they are supposed to be maintained under refrigeration, the Commissioner believes that there is a great danger that at some point these products might be held at ambient temperature long enough to allow the growth of *C. botulinum*. Therefore, he proposes to exclude from introduction into interstate commerce those products that have a pH greater than 4.6, are packaged in hermetically sealed containers, and purport to be pickles.

The Commissioner, therefore, proposes to establish a current good manufacturing practice regulation for the manufacture and processing of pickled, fermented, and acidified foods. If adopted, this regulation would supplement Part 128 (21 CFR Part 128) and set forth additional standards for evaluating the methods and procedures used in the manufacture, processing, packaging, or holding of these products.

Because regulations concerning good manufacturing practice for pickled and acidified foods are to be placed in a new Part 128g (21 CFR Part 128g) it will be necessary to remove them from Part 128b (21 CFR Part 128b). Elsewhere in this issue of the FEDERAL REGISTER is a proposed amendment to Part 128b to delete therefrom acidified foods and to make other needed changes. Also in this issue of the FEDERAL REGISTER, a new emergency permit control regulation concerning pickled, fermented, and acidified foods is proposed. Until orders effectuating these proposals become effective, manufacturing practices for low-acid fruits, vegetables, and vegetable products in which, for the purpose of thermal processing, the pH value is reduced by acidification, must comply with the requirements of Part 128b and § 90.20 (21 CFR 90.20).

This proposal also calls for training supervisory personnel at schools approved by the Commissioner. A reasonable time period to permit such training will be allowed after the regulation is finalized.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. The Commissioner has also carefully considered the inflation impact of the proposed regulation as required by Executive Order 11821, OMB Circular A–107, and interim guidelines issued April 1, 1975 by the Department of Health, Education, and Welfare, and no major inflation impact has been found. Copies of the FDA environmental and inflation impact assessments are on file with the Hearing Clerk, Food and Drug Administration.

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Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding a new Part 128g to read as follows:

PART 128g—PICKLED, FERMENTED, AND ACIDIFIED FOODS

Sec.

128g.1 Definitions.
128g.2 Current good manufacturing practice.
128g.3 Plant and grounds.
128g.4 Equipment and utensils.
128g.5 Personnel sanitation facilities.
128g.6 Equipment and utensil cleaning and sanitizing.
128g.7 Processes and controls.
128g.8 Records.
128g.9 Methodology.
128g.10 Deviations from scheduled procedures.
128g.11 Personnel.

AUTHORITY: Secs. 402(a)(3) and (4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(3) and (4), 371(a)).

§ 128g.1 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Acidified foods" means foods prepared from low-acid food ingredients with or without other food ingredients; they include, but are not limited to,

beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers and fish, singly or in any combination; they are acidified to a pH of 4.6 or lower to prevent growth of microorganisms of public health significance. These foods may be called, or may purport to be "pickles" or "pickled _____." Carbonated beverages and salad dressings are excluded from the coverage of this part.

(b) "Fermented foods" means foods that have been prepared from low-acid ingredients and fermented to an equilibrium pH value of 4.6 or lower. These foods may be called, or may purport to be, such foods as "green olives," "pickles," "pickled _____" or "sauerkraut." The fermented product may be partially desalted, processed, or preserved in the original salt brine or in a new salt brine solution or in a vinegar solution with other ingredients of various compositions to give the characteristics of the particular type of food. Fermented dairy products are excluded from the coverage of this part.

(c) "Lot" means the product produced during a period indicated by a specific code.

(d) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH value greater than 4.6 and a water activity (a_w) greater than 0.85.

(e) "Pickled foods" means foods which are acidified or fermented, as defined in paragraphs (a) and (b) of this section, and which may purport to be "pickles" or "pickled _____."

(f) "Pickle stock" means unprocessed fruits or vegetables on hand which are intended for processing into pickled, acidified, and fermented products.

(g) "Salt stock" means brined lactic-acid-fermented pickle stock, which is cured to an equilibrium pH of 4.6 or lower and has a salt content of 10 percent or more.

(h) "Scheduled process" means the process selected by a processor as adequate for use under the conditions of manufacture for a product in achieving and maintaining a product that will not permit the growth of microorganisms having public health significance. It shall include: a method for controlling pH; conditions for heat processing; maintenance of adequate salt, sugar and preservative levels, as necessary; and storage and container integrity conditions.

(i) "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(j) "Tank yard" means an assortment of vats, barrels or tanks located at a processing plant where fruits and vegetables undergo fermentation in a controlled concentration of salt solution. "Salting station" means a "tank yard" that is not located at the processing plant.

(k) "Waste" means a food product rejected due to adulteration that renders it unsuitable for use as human food.

(l) "Water activity" (a_w) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 128g.2 Current good manufacturing practice.

(a) The criteria in §§ 128g.3 through 128g.11, as well as the criteria in Part 128 of this chapter, shall apply in determining whether an article of pickled, fermented or acidified food is adulterated (1) within the meaning of section 402(a)(4) of the act (21 U.S.C. 342(a)(4)) in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, or (2) within the meaning of section 402(a)(3) of the act (21 U.S.C. 342(a)(3)) in that it has been manufactured under such conditions that it is unfit for food.

(b) Pertinent criteria from Part 128 of this chapter have been amplified in §§ 128g.3 through 128g.11 to emphasize critical control points in the manufacture, processing, packing, or holding of pickled, fermented or acidified foods.

§ 128g.3 Plant and grounds.

(a) *Plant construction.* Special attention shall be given to the fit to doors and windows, soundness of the foundations and walls, and screening on windows and doors to ensure effective protection against the entry of insects, birds, rodents, and other animals.

(b) *Plant design.* Effective measures shall be taken to prevent contamination of products, raw materials, ingredients, and packaging materials with microorganisms, chemicals, filth, or other extraneous material. This may be accomplished by the following or other effective means:

(1) Separating the raw material area from the finished product area by partition, location, air flow or other effective means.

(2) Using protective coverings.

(3) Keeping electric lights from being directly over tanks.

(4) Controlling areas over and around the tanks to eliminate harborages for birds and rodents.

(5) Checking daily the barrels, tanks, vats and other containers holding pickle stock for insect infestation, and checking especially for the various stages of drosophila fly infestation.

(6) Skimming vats frequently.

(7) Using protective coverings over salt bins and tanks.

(8) Washing tanks and covers with a suitable cleaning agent and removing such agent prior to filling the tanks.

(9) Maintaining adequate drainage around the tanks.

(10) Keeping the area around tanks free from contaminating materials.

§ 128g.4 Equipment and utensils.

(a) Food-contact surfaces shall be corrosion-free and made of nontoxic material that will not crack or disintegrate in normal operation and that will withstand the environment of its intended use and the action of food ingredients, cleaning compounds, and sanitizing agents. All food-contact surfaces shall be maintained to prevent product contamination and shall be in compliance with section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) as it pertains to indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to prevent microbiological contamination in places where dirt or organic material might accumulate.

(c) Equipment surfaces which do not come in contact with food shall be so constructed that they can be kept in a clean condition.

(d) Instruments used to test or control temperature or other plant operations shall be properly maintained and kept accurate.

(e) Instruments used to control or measure salt content and pH or acidity and other instruments used to control or prevent undesirable microbial growth in products, shall be properly maintained and kept accurate. Records of the results of periodic testing or calibration of such instruments shall be maintained.

§ 128g.5 Personnel sanitation facilities.

(a) Adequate and readily accessible hand washing and sanitizing facilities shall be provided in the plant for employees who may handle unprotected food, unprotected packaging materials, and food-contact surfaces. Such facilities shall be furnished with running water at a temperature suitable for hand washing, effective hand cleaning and sanitizing preparations, sanitary towel service or suitable drying devices and, where appropriate, refuse receptacles that are constructed and maintained so as to preclude contamination of the products. These facilities should be equipped with water control valves so designed and constructed as to prevent recontamination of cleaned hands.

(b) Readily understandable signs directing employees handling unprotected food, unprotected packaging materials, or food-contact surfaces to wash and sanitize their hands before starting work, after each absence from post of duty, and when their hands have become soiled or contaminated, shall be conspicuously posted in processing room(s) and in all other areas where employees may handle such food, materials or surfaces.

(c) Management shall ensure that employees handling unprotected food, unprotected packaging materials, or food-contact surfaces wash and sanitize their hands before starting work, after each absence from post of duty, and when their hands may have become soiled or contaminated.

§ 128g.6 Equipment and utensil cleaning and sanitizing.

(a) Cleaning and sanitizing of utensils and equipment shall be carried out so as to prevent contamination of raw materials, packaging material, or finished products.

(b) Poisonous or dangerous cleaning compounds, sanitizing agents, and pes-

ticide chemicals shall be applied, stored, and held so as to prevent contamination of food or packaging material. These materials shall be identified and used only in such manner and under conditions that will be safe for their intended use. Any applicable regulations promulgated by the Environmental Protection Agency for the application, use, or holding of such materials shall be followed.

(c) Food-contact surfaces of equipment used for processing or holding product during processing shall be kept sanitary.

§ 128g.7 Processes and controls.

The manufacturer shall employ appropriate quality control procedures and treatments to ensure that raw materials and finished products are wholesome and fit for food, that packaging materials are safe and suitable:

(a) *Handling of raw materials.* (1) Raw materials shall be held in containers designed and constructed to prevent contamination.

(2) Raw materials and packaging materials shall be held under such conditions and at such temperature and relative humidity so as to prevent adulteration and decomposition.

(3) The manufacturer shall ensure that spices, herbs, salt and other raw materials susceptible to infestation or contamination by animals, birds, vermin, microorganisms, or extraneous material comply with current Food and Drug Administration regulations, guidelines, and action levels before these materials are incorporated into finished products. Compliance with this requirement may be accomplished by purchasing these materials under a supplier's guarantee or certification or by analyzing these materials by acceptable methods.

(4) The manufacturer shall take measures to prevent the use of decomposed or otherwise unsuitable products. This may be done by inspecting the raw product for evidence of insects, mold, decay, foreign materials and other defects and by removing the faulty product. Raw products intended for fresh-pack pickles or acidified foods should be washed, if necessary, to remove foreign matter.

(b) *Fermentation and salt curing.* Temperature, salt concentration and acidity are important factors in controlling the fermentation and salt-curing of foods. Controlling the concentration of salt will allow desirable bacteria to proliferate and ferment the food carbohydrate to lactic acid, which, together with the salt, inhibits the growth of bacteria having a potential hazard to health.

(1) The scheduled salting/brining process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience.

(2) The progress and control of the fermentation shall be monitored by appropriate tests. The concentration of salt in the brine shall be determined by a physical test, such as a specific gravity or conductivity test, at sufficient intervals to assure the control of the fermentation. The progress of the fermentation shall be indicated by pH measurements or acid/base titrations or both according to the methods set forth in § 128g.9 at sufficient intervals to assure the control of the fermentation.

(3) At the completion of fermentation, the concentration of salt shall be sufficient to prevent the growth of *C. botulinum* when the product is held at room temperature.

(4) Salt curing, which may be accompanied by slow fermentation, shall be done by placing the fresh food in a solution having a salt concentration sufficiently high to prevent the growth of *C. botulinum*.

(c) *Processing operations.* The manufacturer shall employ appropriate quality control procedures to ensure that finished products do not present a health hazard.

(1) Pickled, fermented, and acidified foods shall be so manufactured, processed, and packaged that an equilibrium pH value of 4.6 or lower is achieved and maintained in all finished products. Manufacturing shall be in accordance with the scheduled procedure. All products that purport to be, or are represented as "pickles," "pickled," or "acidified," shall have an equilibrium pH of 4.6 or lower unless they are thermally processed as low-acid foods under Part 128b of this chapter.

(2) Sufficient control, including frequent testing and recording of results, shall be exercised so that the equilibrated pH values for pickled, fermented and acidified foods are not higher than 4.6. This shall be verified by a qualified analyst using a suitable method. A method based upon a potentiometric method such as that described under § 128g.9(a) shall be employed if the pH values are higher than 4.0. If the pH is 4.0 or lower, colorimetric methods may be used. If a procedure based upon titratable acidity is to be used during process operations, the manufacturer shall relate results obtained by the particular method used to the equilibrated pH of the final product. Special care should be taken when food ingredients have been subjected to lye, lime, or similar high pH materials.

(3) Procedures for acidification to attain acceptable PH levels in the final product include, but are not limited to, the following:

(i) Blanching of the food ingredients in acidified aqueous solutions.

(ii) Immersion of the blanched food ingredients in acid solutions. Although immersion of food ingredients in an acid solution is a satisfactory method for acidification, care must be taken to assure that the acid concentration is properly maintained.

(iii) Direct batch acidification. This can be achieved by adding a known amount of an acid solution to a specified amount of product during acidification.

(iv) Direct addition of a predetermined amount of acid to individual containers during production. Liquid acids are generally more effective than solid or pelleted acids. Care must be taken to ensure that the proper amount of acid is added to each container.

(v) Addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations.

(4) When the salt concentration of the brine in tanks containing food may have been significantly diluted by rain, it should be checked and adjusted as necessary.

(5) Effective measures shall be taken to prevent the inclusion of metal, wood, glass or other extraneous material in finished products. This may be accomplished by using suitable equipment such as sieves, magnets, electronic metal detectors, or other effective means.

(6) The final packaging operation shall be in an enclosed building. Testing and examinations of containers shall occur often enough to ensure that the container suitably protects the product from leakage or contamination.

(7) Waste shall be prevented from contributing to direct or indirect product contamination. This may be accomplished by holding the waste in properly identified containers and removing it from the plant at least once per day.

(d) *Coding.* Each container or product shall be marked with an identifying code that shall be permanently visible to the naked eye. Where the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, provided that the label is securely affixed to the product container. The required identification shall specify in code the establishment where the product was packed, the product contained therein, and the year, day, and period during which it was packed. The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution. Codes may be changed periodically on one of the following bases: intervals of 4 to 5 hours; personnel shift changes; or batches, provided the containers comprising such batch do not represent those processed during more than one personnel shift.

§ 128g.8 Records.

(a) In accordance with paragraph (e) of this section, records shall be maintained of: examinations of raw materials, packaging materials, and finished products; and of suppliers' guarantees or certifications that verify compliance with Food and Drug Administration regulations and guidelines or action levels.

(b) Processing and production records covering processes intended to pasteurize or otherwise heat treat products, and records of pH measurements, temperature, salt concentration, and other critical factors intended to ensure a safe product, shall be maintained and shall contain sufficient additional information such as product code, date, container size and product, to permit a public health hazard of evaluation of the processes applied to each lot, batch or other portion of production.

(c) All departures from scheduled processes having a possible bearing on public health or the safety of the food shall be noted and the affected portion of the product identified; such departures shall be recorded and made the subject of a separate file delineating them, the action taken to rectify them, and the disposition of the portion of the product involved.

(d) Records shall be maintained identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

(e) Copies of all records provided for in this part shall be retained at the processing plant or other reasonably accessible location for an additional 2 years.

§ 128g.9 Methodology.

Methods that may be used to determine pH or acidity for pickled, fermented and acidified foods include, but are not limited to, the following:

(a) *Potentiometric method for the determination of pH.* This method must be used if the pH is higher than 4.0.

(1) *Principles.* The term "pH" is used to designate the intensity or degree of acidity. The value of pH, the logarithm of the reciprocal of the hydrogen ion concentration in solution, is determined by measuring the difference in potential between two electrodes immersed in a sample solution. A suitable system consists of a potentiometer, a glass electrode, and a reference electrode. A precise pH determination can be made by making an electromotive force (emf) measurement of a standard buffer solution whose pH is known, and then by comparing that measurement to an emf measurement of a sample of the solution to be tested.

(2) *Instruments.* The primary instrument for use in pH determination is the pH meter or potentiometer. For most work, an instrument with a direct-reading pH scale is necessary. Battery and line-operated instruments are available commercially. Line-operated instruments should be fitted with voltage regulators to eliminate drifting of meter-scale readings. Batteries should be checked frequently to assure proper operation of battery operated instruments. An instrument using an expanded unit scale or a digital readout system is preferred since it allows more precise measurements.

(3) *Electrodes.* The typical pH meter is equipped with a glass membrance electrode and a reference electrode. Various types of electrodes designed for specific uses are available. The most commonly used reference electrode is the calomel electrode, which incorporates a salt bridge filled with saturated potassium chloride solution.

(i) *Care and use of electrodes.* Calomel electrodes should be kept filled with saturated potassium chloride solution, because they may become damaged if they are allowed to dry out. For best results, electrodes should be soaked in boiled distilled water for several hours before using and kept ready by storing with tips immersed in distilled water or in buffer solution used for standardization. Electrodes should be rinsed with boiled distilled water before immersing in the standard buffers and between sample determinations. A lag in meter response may indicate aging effects or fouling of the electrodes, and cleaning and rejuvenation of the electrodes may be necessary. This may be accomplished by placing the electrodes in 0.1 molar sodium hydroxide solution for 1 minute and then transferring them to 0.1 molar hydrochloric acid solution for 1 minute. The cycle should be repeated two times, ending with the electrodes in the acid solution. The electrodes should then be thoroughly rinsed with distilled water and blotted with soft tissue before proceeding with the standardization.

(ii) *Temperature.* To obtain accurate results, a uniform temperature should be maintained for the electrodes, the standard buffer solutions, and the samples. Tests should be made at a temperature between 20° to 30° C, the optimum being 25° C. Any temperature determinations made without meter compensation may vary pH values.

(iii) *Accuracy.* The accuracy of most pH meters is stated to be approximately 0.1 pH unit, and reproducibility is usually ±0.05 pH unit or less. Some meters permit the expansion of any pH unit range to cover the entire scale and have an accuracy of approximately of ±0.01 pH unit and a reproducibility of ±0.005 pH units.

(4) *General procedure for determining pH.* When operating an instrument, the manufacturer's instructions should be used and the following techniques for pH determinations observed:

(i) Switch the instrument on and allow the electronic components to warm up and stabilize before proceeding.

(ii) Standardize the instrument and electrodes with commercially-prepared standard 4.0 pH buffer or with freshly prepared 0.05 molar potassium acid phthalate buffer solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, section 50.007 (c), page 943.[1] Note the temperature of the buffer solution and set the temperature compensator control at the observed temperature (room temperature is near 25° C).

(iii) Rinse the electrodes with recently-boiled distilled water and blot but do not wipe with soft tissue.

(iv) Immerse the tips in the buffer solution and take the pH reading, allowing about 1 minute for the meter to stabilize. Adjust the standardization control so that the meter reading corresponds to the pH of the known buffer (for example, 4.0) for the temperature observed. Rinse the electrodes with boiled distilled water and blot with soft tissue. Repeat procedure with fresh portions of buffer solution until the instrument remains in balance on two successive trials. To check the operation of the pH meter, check the pH reading using another standard buffer such as one having a pH of 7.0 or check it with freshly prepared 0.025 molar phosphate solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, section 50.007(e), page 943.[1] Expanded scale pH meters may be checked with pH 3.0 or pH 5.0 standard buffers. Buffers and instruments can be further checked by comparison with values obtained with a second properly standardized instrument.

(v) Indicating electrodes may be checked for proper operation by first using an acid buffer then a base buffer. First standardize the electrodes using a pH 4.0 buffer at or near 25° C. Standardization control should be adjusted so that the meter reads exactly 4.0. Electrodes should be rinsed with distilled water, then blotted and immersed in a pH 9.18 borax buffer prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, section 50.007(f), page 943.[1] The pH reading should be within ±0.3 units of the 9.18 value.

(vi) The pH meter can be tested for proper operation by shorting the glass and reference electrode inputs, thereby reducing the voltage to zero. In some meters this is done by switching the instrument to standby, and in other instruments by use of a shorting strap. With the instrument shorted out, standardization control should be turned from one extreme to another. This operation should produce a deflection greater than ±1.5 pH unit from center scale.

(5) *Determining pH on samples.* (i) Adjust the temperature of the sample to room temperature (25° C), and set the temperature compensator control to the observed temperature. With some expanded scale instruments, the sample temperature must be the same as the temperature of the buffer solution used for the standardization.

(ii) Rinse and blot the electrodes. Immerse the electrodes in the sample and take the pH reading, allowing 1 minute for the meter to stabilize. Rinse and blot the electrodes and repeat on a fresh portion of sample. Oil and grease from the samples may coat the electrodes, so it is advisable to clean and standardize the instrument frequently, usually after three determinations. When oily samples cause fouling problems, it may become necessary to rinse the electrodes with ethyl ether.

(iii) Determine two pH values on each of two portions or areas of the well-mixed sample. These readings should be in agreement with one another to indicate that the sample is homogeneous. Report values to the nearest 0.05 pH unit.

(6) *Preparation of samples.* Some food products may consist of a mixture of liquid and solid components that differ in acidity. Other food products may be semi-solid in character. The following are ex-

[1] Copies may be obtained from: Association of Official Analytical Chemists P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044.

amples of preparation procedures for pH testing for each of these categories:

(i) *Liquid and solid component mixtures.* Drain the contents of the container for 2 minutes on a U.S. standard No. 8 sieve (preferably stainless steel) inclined at a 17- to 20-degree angle. Record weights of the liquid and solid portions and retain each portion separately.

(A) If the liquid contains sufficient oil to cause electrode fouling, separate the layers with a separatory funnel and retain the aqueous layer. The oil layer may be discarded. Adjust the temperature of the aqueous layer to 25° C and determine its pH.

(B) Remove the drained solids from the sieve, blend to a uniform paste, adjust the temperature of the paste to 25° C and determine its pH.

(C) Mix aliquots of solid and liquid fractions in the same ratio as found in the original container and blend to a uniform consistency. Adjust the temperature of the blend to 25° C and determine the equilibrated pH.

(ii) *Marinated oil products.* Separate the oil from the solid product. Blend the solid in a blender to a paste consistency; it may become necessary to add a small amount of recently-boiled distilled water to some samples to facilitate the blending. A small amount of added water will not alter the pH of most food products, but caution must be exercised concerning poorly buffered foods. No more than 20 milliliters of distilled water should be added to each 100 grams of product. Determine the pH by immersing electrodes in the prepared paste after adjusting the temperature to 25° C.

(iii) *Semi-solid products.* Food products of a semi-solid consistency such as puddings, potato salad, etc., may be blended to a paste consistency, and the pH may be determined on the prepared paste. Where more fluidity is required, 10 to 20 milliliters of boiled distilled water may be added to 100 grams of product. Adjust the temperature of the prepared paste to 25° C and determine its pH.

(iv) *Special product mixtures.* For special product mixtures such as antipasto, pour off the oil, blend the remaining product to a paste and determine the pH of the blended paste. Where more fluidity is required, add 10 to 20 milliliters of boiled distilled water to each 100 grams of product and blend. Adjust the temperature of the prepared paste to 25° C and determine its pH.

(7) *Process pH determination.* Obtain sample portions of material for pH determination.

(i) For process liquids, adjust the temperature of the liquid to 25° C and determine the pH by immersing the electrodes in the liquid.

(ii) Drain solid materials on a sieve and blend to a workable paste. Adjust the temperature of the prepared paste to 25° C and determine its pH.

(iii) Where enough solid materials are available to make a paste, blend representative aliquots of liquid and solid materials to a workable paste. Adjust the temperature of the prepared paste to 25° C and determine the equilibrated pH.

(b) *Colorimetric method for the determination of pH.* This method may be used in lieu of potentiometric method if the pH is 4.0 or lower.

(1) *Principle.* The colorimetric method for pH involves the use of indicator dyes in solution that gradually change color over limited pH ranges. An indicator that has the greatest color change at approximately the pH of the sample being tested is selected. The pH is determined by the color of the indicator when exposed to the sample under test.

(2) *Indicator solutions.* Most indicator solutions are prepared as a 0.04 percent solution of the indicator dye in alcohol. In testing, a few drops of indicator solution are added to 10-milliliter portions of the sample solution. Colors should be compared using a bright background. Approximate determinations can be made on white porcelain spot plates, the test colors being compared thereon with a set of color standards. More accurate colorimetric tests can be made using a comparator block fitted with sets of tubes of standard indicator solutions of known pH.

(3) *Indicator paper.* A paper tape treated with indicator dye is dipped into the sample solution. Depending upon the pH of the solution, the tape will change color and an approximate pH can be determined by comparison with a standard color chart.

(c) *Titratable acidity.* Acceptable methods for determining titratable acidity are described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975, sections 22.060–22.061 page 401.[1] The procedure for preparing and standardizing the sodium hydroxide solution is described in "the same publication," sections 50.032–50.035, page 946.[1]

§ 128g.10 Deviations from scheduled processes.

Whenever any process operation deviates from the scheduled processes for any pickled, fermented or acidfied food and whenever the equilibrium pH value of the finished product is higher than 4.6 as disclosed from records, as determined by a qualified analyst or otherwise, the commercial processor of such pickled, fermented or acidfied food shall either: (a) Fully rework the deviant portion of the product by the scheduled process (or another process established as adequate to assure a safe product), which includes but is not limited to acidification, reprocessing and keeping full records of the processes used for reworking; (b) or thermally process it as a low-acid food pursuant to Part 128b of this chapter. Alternatively, that portion of the product involved shall be set aside for further evaluation as to any potential public health significance.

Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless such evaluation demonstrates that the product has undergone a process that has rendered it safe, the product set aside shall either be fully reprocessed to render it safe or destroyed. A record shall be made of the procedures used in the evaluation and the results. Either upon completion of full reworking and the attainment of a safe product or after the determination that no significant potential for public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed.

§ 128g.11 Personnel.

All operators of processing and packaging systems shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction.

Interested persons may, on or before September 21, 1976, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 2, 1976.

SHERWIN GARDNER,
Deputy Commissioner of Food and Drugs.

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See footnote on p. 30461.